DEC - 4 2003

General Electric Medical Systems

K033400

Seno Advantage
510 (k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87 (h)

1. **Identification of submitter:**

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GE Medical Systems W-400
3000 North Grandview Blvd.
Waukesha, WI 53188 USA
Date Prepared: August 4, 2003

2. **Identification of Product:**

Device name	Seno Advantage
Classification Panel:	Radiology PACS per 21CFR Section 820 2050
Manufacturer/ Distributor	General Electric Medical Systems 283, Rue de la Minière 78533 BUC Cedex France

3. **Marketed Devices**

Seno Advantage is substantially equivalent to the devices listed below:

Model:	Advantage Windows Review Workstation
Manufacturer:	General Electric Medical Systems
510 (k):	K020483

4. **Device Description :**

The Seno Advantage Workstation is a multi-modality review workstation. It includes a color flat panel for the multi-modality image review and two specific B&W high resolution

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monitors for the mammographic images review. Moreover, a dedicated keypad is provided to increase productivity.

The Seno Advantage is positioned to be the system of choice for all users of Modality: CT, MR, XR, RF, XA, CR, DX, MG, NM, PET, US, SC.

The Hardware configuration of Seno Advantage is the following:

- HP XW8000 Workstation:
  - Dual Intel® Xeon™ Processor
  - 2 x 3.06GHz CPU Clock Speed with 512KB Cache per CPU
  - 2GB RAM (expandable to 4GB)
  - 2 x 73 GB: Ultra160 SCSI 15,000rpm Hard Disks
  - 130 GB can be used for image storage as follows:
    - 991,821 256^2 images OR
    - 247,995 512^2 images OR
    - 61,989 1024^2 images OR
    - 12,398 2048 x 2560 images
  - Internal CD-ROM drive (48x read/write) for read/write of DICOM media, read/write of Data Export data and service use.
  - 1 internal 3½" Floppy Drive
  - 1 US QWERTY Keyboard.
  - 1 mechanical 3-buttons mouse
  - 1 Mammography dedicated keypad.
  - 1 B&W Video board 5Mpixels Dual Head

- Monitors specifications : Two types of monitors are used. Specifications for each of these monitors is given here:
  - 1 NEC* Flat Panel 18.1" LCD
  - NEC MultiSync* LCD1880SX
  - 18.1 inch diagonal width
  - 1280x1024 Landscape display
  - 60 Hz refresh rate
  - Height: 44.5cm (17.5in.)
  - Width: 39.8cm (15.7in.)
  - Depth: 21.8cm (8.6in.)
  - Weight: 8.5kg (18.7lb.)
  - 110-240VAC, 47-63Hz, 0.35-0.8Amps.
  - 2 Graysacale 5 Mpixels CRT
  - 21 inch diagonal width
  - 2560x2048 portrait display

- 76 Hz refresh rate
- Height: 52cm (20.4in.)
- Width: 40.5cm (16in.)
- Depth: 50.5cm (19.8in.)
- Weight: 35kg (78.7lb.)
- 110-240VAC, 47-65Hz

Seno Advantage supports the following image networking:

- Standard Standard 10/100/1000 Base-T Ethernet Protocols supported:
- DICOM 3.0 Storage SCU/SCP and Query/Retrieve SCU/SCP
- InSite
- TCP/IP network layer
- SdCNet supported to query/retrieve from AW 3.1 and AW 4.0

5. Indications for Use

Seno Advantage is a medical image review station that allows easy selection, processing, filming and media interchange of multi-modality images from a variety of diagnosis imaging systems. When interpreted by a trained physician, mammographic images displayed on the high-resolution monitors may be used as an element for diagnosis. Furthermore filmed images from all modalities may also be used as an element for diagnosis.

6. Comparison with Predicate Device

The Seno Advantage is substantially equivalent to the following workstation:
Advantage Workstation 4.1
Manufacturer: GE Medical Systems
510(k): K020483
Both of these workstations allow easy selection, review, processing, filming and media interchange of multi-modality images from a variety of diagnosis imaging systems.

7. Conclusions

Seno Advantage brings additional features in order to integrate seamlessly into the Radiology Department Workflow. The entire potential new hazards has been studied and controlled by a Risk Management Plan:

- A hazard analysis/ Risk Management Summary
- A software development and validation process

- A software verification plan

Seno Advantage provides images comparable to the predicate device.

8. Other – table of acronyms

In the whole submission, the DICOM acronyms are used to describe the various imaging modalities supported by the Seno Advantage workstation. The following table defines these acronyms:

Term	Definition
CR (modality)	Computerized Radiology or Computed Radiography
CRT	Cathode Ray Tube
CT (modality)	Computerized Tomography
DICOM (standard)	Digital Imaging and Communications in Medicine
DX (modality)	Digital Xray
MG (modality)	Digital Mammography
MR (modality)	Magnetic Resonance
MX (modality)	MiXed modality (i.e. the exam contains series of different modalities)
NM (modality)	Nuclear Medicine
OT (modality)	OTher modality
PET or **PT** (modality)	Positron Emission Tomography
RF or **XRF** (modality)	Xray Radio &Fluoro
RT (modality)	Radiation Therapy
SC or **SCPT** (modality)	Secondary Capture
SR (modality)	Structured Report
US (modality)	Ultra Sound
XA (modality)	Xray Angio (vascular and cardio exams)
XR (modality)	Xray

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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GE Medical Systems W-400
% Mr. Juergen Welte
Acting Program Manager 510(k)
TUV Rheinland of North America
12 Commerce Road
NEWTON CT 06470

Re: K033400
Trade/Device Name: Seno Advantage
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communication system
Regulatory Class: II
Product Code: 90 LLZ
Dated: November 18, 2003
Received: November 19, 2003

Dear Mr. Welte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATION FOR USE

K033400

Device name: Seno Advantage

Indication for use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ -OR- Over-The-Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033400